REMARKS

Applicants appreciate the through examination of the present application as evidenced by the Office Action dated January 28, 2004 (hereinafter, "the Office Action"). Claims 12-15, 19-21, 23-26 and 31-33 are pending in the present application upon entry of the present Amendment. The concerns raised by the Examiner in the Office Action are addressed below.

I. Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 12-15, 19-21, 23-26 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking written description. In particular, the Office Action alleges that "[t]he limitation of a subject 'at risk of developing' recited in claims 12 and 21 has no clear support in the specification and the claims as originally filed." Office Action, page 3.

Applicants respectfully disagree with this assertion. However, in an effort to expedite prosecution, Applicants have deleted the recitation "at risk of developing," thereby obviating this rejection. Accordingly, Applicants respectfully request that this rejection be withdrawn.

II. Claim Rejections Under 35 U.S.C. § 102

Claims 12-15, 19-21, 23-27 and 29 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Bukowski et al. *Blood.* **84 (No. 1, Suppl. 1)**: 129a (1994) (hereinafter, "Bukowski et al."). *See* Office Action, page 2. The Office Action states that "[t]he method of the prior art comprises the same method steps as claimed in the instant invention, that is administering erythropoietin in conjunction with cisplatin to the same population, that is patients with solid vascularized tumors at the same dosage, thus the method is anticipated because the method will inherently lead to the enhanced suppression of endothelial growth associated with the administration of cisplatin." Office Action, page 5. Applicants respectfully disagree.

Contrary to the assertions of the Office Action, the patient population in Bukowski et al. is not the same patient population as indicated in the present application. In particular, the patient population in Bukowski et al. is anemic cancer patients. Also, the patients in Bukowski et al. are described as being diagnosed with various tumor types including hematologic and non-hematologic tumor types. The

patient population of the present invention is not recited as being anemic cancer patients. Moreover, amended Claims 12 and 21 specifically recite that the "subject is afflicted with a solid vascularized tumor selected from cerebellar hemangioblastoma, ductal carcinoma of the breast or squamous cell cancer of the larynx." As noted in the Office Action, Bukowski et al. "does not specifically teach that the patients with various types of cancer include cerebellar hemangioblastoma, ductal carcinoma of the breast or squamous cell cancer of the larynx." Office Action, page 7.

In view of the different patient population subjected to the treatment in Bukowski et al., Applicants respectfully submit that the method described in Bukowski et al. would not inherently lead to enhanced suppression of endothelial growth associated with administration of cisplatin in the distinct patient population intended in the present invention.

Claims 27-29 stand rejected under 35 U.S.C. § 102(b) in view of *Proc. Am. Soc. Clin. Oncol.* 1994, 13, 30 Meet, 234. to Bokkel et al. (hereinafter, "Bokkel et al."). *See* Office Action, page 6. In order to expedite prosecution, Applicants have canceled Claims 27-29 thereby obviating the rejection of Claims 27-29 as being anticipated by Bokkel et al.

Accordingly, Applicants respectfully request withdrawal of the rejection of Claims 12-15, 19-21 and 23-26 under 35 U.S.C. § 102(b) in view of the cited references, and respectfully submit that new Claims 31-33 are not anticipated by the cited references.

III. Claim Rejections Under 35 U.S.C. § 103

Claims 12-15, 19-21 23-27 and 29 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Bukowski et al. *See* Office Action, page 7. More specifically, The Office Action states the following:

> However, if not included in the treatment groups, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have included patients with cerebellar hemangioblastoma, ductal carcinoma of the breast or squamous cell cancer of the larynx in the combined therapy treatment of cancer patients receiving chemotherapy and erythropoietin because it is clear from the information in the reference that the combination treatment is a pan cancer treatment which was successful over a wide range of cancer types. Thus, one would have a reasonable expectation of success in treating

> patients with cerebellar hemangioblastoma, ductal carcinoma of the breast or squamous cell cancer of the larynx with the protocol and the enhancement of endothelial growth suppression associated with administration of cisplatin would be intrinsic.

Office Action, page 8. Applicants respectfully disagree.

Applicants respectfully submit that one of ordinary skill in the art would not have a reasonable expectation of success of treating patients with cerebellar hemangioblastoma, ductal carcinoma of the breast or squamous cell cancer of the larynx with the protocol described in Bukowski et al. where, among other things, the patients described in Bukowski et al. are anemic cancer patients, and further, Bukowski et al. alleges that a non-specific cancer patient population experienced improved energy level, activity level and overall well-being. These clinical outcomes are indications that their anemic condition may have improved which is the focus of the Bukowski et al. study. Accordingly, a study directed to improving symptoms and clinical outcomes associated with anemia does not provide motivation to modify the protocol to provide treatment of solid vascularized tumors as recited in the claims of the present application.

Accordingly, Applicants respectfully submit that Claims 12-15, 19-21, 23-26 and new Claims 31-33 are not obvious in view of Bukowski et al. Applicants further respectfully request that the rejection of Claims 12-15, 19-21 and 23-26 be withdrawn.

Conclusion

Applicants respectfully submit that, for the reasons discussed above, the references cited in the present rejections do not disclose or suggest the present invention as claimed. Accordingly, Applicants respectfully request allowance of all the pending claims and passing this application to issue.

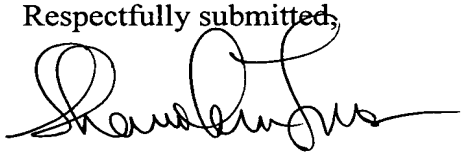
It is not believed that any fee(s), including fees for additional claims, are required, beyond those that may otherwise be provided for in documents accompanying this paper.

In the event, however, that additional fees are necessary to allow consideration of this paper, such an extension is also hereby petitioned for under 37 C.F.R. §1.136(a). Any

additional fees believed to be due in connection with this paper may be charged to our Deposit Account No. 50-0220.

The Examiner is invited and encouraged to contact the undersigned directly if such contact will expedite the prosecution of the pending claims to issue. In any event, any questions that the Examiner may have should be directed to the undersigned, who may be reached at (919) 854-1400.

Respectfully submitted,



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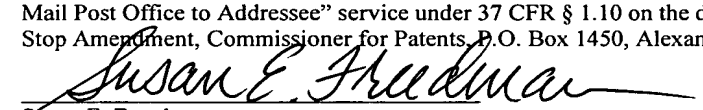

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